

## REMARKS

Applicant respectfully requests favorable reconsideration of this application in light of the following remarks. By the present amendment Applicant has amended claim 12. Claims 12-34 remain pending in this application. No new matter has been added.

### 35 U.S.C. § 112 Rejection

In the Office Action, claim 12 was rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicant has amended claim 12 to replace "an end of the sealing portion" with "a distal end of the sealing portion" to comply with the Examiner's suggestion. Applicant has also further amended claim 12 for additional clarification of structural relationship, support for which is found at least in Figs. 2 and 5 of the originally filed application.

For at least the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 12 under 35 U.S.C. §112, second paragraph.

### 35 U.S.C. § 102(b) Rejections

In the Office Action, claims 12, 13, 15, 19, 22, 24, and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,374,264 to Wadsworth, Jr. (hereinafter "Wadsworth"). Applicant respectfully traverses this rejection.

Independent claim 12 recites a fluid transfer device, including, among other things, a piercing mandrel, "wherein the piercing mandrel further includes a sealing portion formed integrally with and extending from the lid portion . . ." As explained in MPEP 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

The Office Action states that the sealing portion 24 of Wadsworth "is formed integrally with the lid portion 14 and contacts the piercing portion." Office Action at 6.

Applicant respectfully disagrees and asserts that "sealing portion 24" is not integrally formed with the lid of Wadsworth. Therefore, this claim element is not found within the four corners of the cited reference.

The specification of Wadsworth explicitly teaches "[a]n elastomeric sheath valve 24 preferably is *attached* to the bottom surface of body portion 14 and surrounds needle 26, including its point 23." Wadsworth, col. 3:3-5 (emphasis added). Further, Applicant points out that each figure of Wadsworth in which sheath valve 24 is present clearly illustrates that sheath valve 24 is a distinct structure from body portion 14. Wadsworth, Figs. 2, 4. Therefore, the disclosure of Wadsworth itself confirms that the sealing portion is not integrated with the lid portion.

In addition, independent claim 12, as amended, recites "wherein, when the bead is substantially disposed in the space, a distance between a base of the sealing portion and a distal end of the sealing portion on the piercing mandrel is more than a length between the base of the sealing portion and the external surface of the elastic stopper within the container." Applicant submits that Wadsworth discloses no such feature because the disclosed sealing portion 24 of Wadsworth may contact the top surface of the stopper but can travel no farther into the stopper. Wadsworth, Fig. 4.

Since Wadsworth discloses neither 1) a sealing portion formed integrally with and extending from the lid portion nor 2) when the bead is substantially disposed in the space, a distance between a base of the sealing portion and a distal end of the sealing portion on the piercing mandrel more than a length between the base of the sealing

portion and the external surface of the elastic stopper within the container, as recited in claim 12, Wadsworth does not anticipate this claim.

Accordingly, for at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 12 under 35 U.S.C. § 102(b).

Claims 13, 15, 19, 22, 24, and 25 depend from claim 12 and are therefore allowable over Wadsworth for at least the same reasons explained above.

### **35 U.S.C. § 103(a) Rejections**

Claims 12-19, 21-23, 26-29, and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Application No. 2002/0121496 to Thiebault et al. (hereinafter "Thiebault") in view of U.S. Patent No. 5,895,383 to Niedospial, Jr. (hereinafter "Niedospial"). Applicant respectfully traverses this rejection.

The Office Action asserts that Thiebault "does not specifically disclose that the sealing portion is formed integrally with and extending from the lid portion," but that Niedospial "discloses a medicament container closure having a recessed integral spike" comprised of "a piercing portion 116 and a sealing portion (above annular groove 113) that are formed integrally with a lid portion 118." Office Action at 4. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicant respectfully asserts that the sealing portion of Niedospial is not formed integrally with and does not extend from the specified lid portion (as disclosed) and therefore this element, which is lacking in Thiebault, also is not within the disclosure of Niedospial.

Thiebault states that “[t]he transfer set 20 of this invention includes three components, namely . . . a housing 40 . . . a piercing member 42 . . . and a cap or closure 44 . . .” Thiebault at [0023]; Fig. 1. In operation, cap 44 is first removed from the set. Piercing member 42 is thereby released from cap 44 when a flange 86 on piercing member 42 engages an abutment surface 53 on inner tubular member 52. At that point, cap 44 is separated from both piercing member 42 and any fluid sealing components remaining in the transfer set. A Luer connector from a second container is attached to distal portion 52b of inner tubular member 52. As this connection is made, the distal end 94 of piercing member 42 is engaged, driving piercing member 42 through the stopper 30, establishing a fluid connection. *Id.* at [0029].

The closure assembly of Niedospial includes a spike access means 100 having a top portion 102 incorporating a spike 110 with a sharp tip 116 at a lower end and a male Luer connector 118 at the other end for connection to intravenous (IV) tubing. Niedospial, col. 6:30-38; Fig. 6. A container with spike access means 100 is capped with a cap 18 (see Fig. 7) that is sealed to the neck of the container with a tear strip 25. *Id.* at col. 6:53-56; Fig. 6. In operation, tear strip 25 is removed and manual force then exerted downward on cap 18. This manual force drives sharp tip 116 of spike 100 through the recessed target area 68 of elastomeric stopper 60. Cap 18 is removed and male Luer connector 118 connected to the IV line. *Id.* at cols. 6:60-67, 7:1-9.

Spike 110 and any structures for sealing described in Niedospial are clearly dissociated from cap 18. In fact, the operation of Niedospial precludes the sealing portion from being integrally formed with cap 18 for precisely the same reason Thiebault lacks this structure. In both pieces of prior art, as described above, the lid is removed

before a fluid connection is possible, yet the sealing structure remains behind. Therefore, Thiebault's deficiency, lack of a sealing portion formed integrally with and extending from the lid portion, is not remedied by the disclosure of Niedospial, as cap 18 is completely separate from the sealing elements. For this reason alone, the rejection of claim 12 should be withdrawn.

The Office Action further contends that “[i]t would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer set having a cylindrical piercing member of Thiebault, et al. with use of an integral sealing member of Niedospial in order to prevent fluids from leaking through the elastic stopper around the outside of the piercing mandrel. . . .” Office Action at 5. As detailed in MPEP 2143.01 VI, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.”

For purposes of the rejection, the Office Action maintains that the cap 18 of Niedospial does not represent the lid of Niedospial. Rather, the Office Action suggests, as noted above, that the lid portion consists of male Luer connector 118. Assuming, *arguendo*, this contention of the Examiner is correct, which Applicant does not concede, Applicant respectfully asserts that modifying the fluid transfer set of Thiebault with the integral sealing member of Niedospial would severely affect the principle of operation of Thiebault.

As described above, Thiebault requires separation of the lid portion from the underlying piercing portion/sealing portion prior to external connection because the outside syringe does not connect to the "lid," of Thiebault (as, for purposes of this

argument only, it does in Niedospial) but directly to the end of the now separated underlying piercing portion. The very fact that the spike and sealing portion of Niedospial are formed integrally with what the Examiner considers the lid of Niedospial prevents its application to the disclosure of Thiebault. In other words, modifying Thiebault with the teaching of Niedospial would significantly change the fundamental principle of operation of Thiebault as described. For this reason, the Examiner has failed to clearly articulate a reason why Thiebault in view of Niedospial would render claim 12 obvious to one of ordinary skill in the art and has not established a *prima facie* case of obviousness with respect to this claim.

Accordingly, for at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 12 under 35 U.S.C. § 103(a).

Claims 13-19, 21-23, and 26-29 depend from claim 12 and are therefore allowable over Thiebault in view of Niedospial for at least the same reasons explained above.

Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Thiebault in view of Niedospial and further in view of U.S. Patent No. 5,358,501 to Meyer (hereinafter “Meyer”). Claim 20 depends from claim 12 and is therefore allowable over Thiebault in view of Niedospial for at least the same reasons explained above. Moreover, Meyer does not remedy the noted deficiencies of Thiebault in view of Niedospial. Accordingly, for this additional reason, the rejection of claim 20 is not sustainable and should be withdrawn.

Claims 30-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Thiebault in view of Niedospial and further in view of U.S. Patent No. 6,558,365 to

Zinger et al. (hereinafter “Zinger”). Claims 30-33 depend from claim 12 and are therefore allowable over Thiebault in view of Niedospial for at least the same reasons explained above. Further, Zinger does not remedy the noted deficiencies of Thiebault in view of Niedospial. Accordingly, for this additional reason, the rejection of claims 30-33 is not sustainable and should be withdrawn.

Independent claim 34 recites a fluid transfer device, including, among other things, a sealing portion ending in a substantially abrupt step “configured to engage and seal the pierced portion of the elastic stopper when the bead is received in the space . . .”

In the Examiner’s Interview Summary of March 26, 2008, the Examiner contends that claim 34 is obvious in view of the prior art because Niedospial discloses that the sealing portion extends downward to create a seal with the stopper and that the sealing portion is stepped such that it transitions from the piercing portion to the sealing portion (see Interview Summary Continuation Sheet).

Applicant respectfully asserts that the sealing portion of Niedospial does not engage and seal the *pierced portion* of the elastic stopper (as disclosed and shown in Fig. 8 of Niedospial) and therefore this element, which is required to establish *prima facie* obviousness of claim 34, is not within the disclosure of Niedospial.

Accordingly, for at least this reason, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 34 under 35 U.S.C. § 103(a).

**Conclusion**

In view of the foregoing reasons, Applicant respectfully requests reconsideration of this application, withdrawal of all of the outstanding rejections, and timely allowance of all pending claims.

The Office Action contains statements and characterizations regarding the claims and the related art. Applicant declines to subscribe automatically to any statement or characterization in the Office Action, regardless of whether it is addressed above.

Please grant any extensions of time required to enter this amendment and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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